

Guide for Quantifying HIV Test Requirements

DELIVER

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Abstract

To date, most HIV/AIDS program interventions have been small-scale, pilot interventions that worked well because a large number of human and financial resources were focused on a small audience. Quantification, procurement, and supply chain management of HIV test kits and other commodities for small programs is less complicated than for larger, more complex programs. Program managers are under increasing pressure to make decisions about allocating funding for the purchase of HIV test kits to support major HIV/AIDS program expansion. Therefore, this guide was developed as a tool for the systematic, accurate quantification of HIV test requirements to help program managers identify their needs and manage their commodities more effectively.

This guide provides background on the use of HIV tests and commonly used testing protocols. It also discusses the steps in and data collection for quantification. Guidance is provided for quantifying for seven different uses for HIV tests. These include ensuring safe blood supply; providing voluntary counseling and testing (VCT) services; preventing mother-to-child transmission (PMTCT); testing HIV-exposed babies; providing clinical diagnosis in hospital and health facility settings; conducting sentinel surveillance; supporting other uses including research, training, and the testing of other specific populations or groups. For each of those uses, guidance is provided for the appropriate quantification methodologies. The methodologies discussed include using logistics or consumption data; demographic and morbidity data; service statistics; and targets. The guide also addresses the need to carefully assess service capacity for both counseling and testing to avoid purchasing more tests than can be administered by a program, resulting in major loss of product through expiration.

The DELIVER project automated the approach to quantifying HIV test requirements described in this guide through the development of a software program called ProQ: Quantification Software for HIV Tests.

The approach in this guide was developed from a variety of sources, including a study of available literature, interviews with those implementing programs in the field, and the experience of DELIVER staff in quantifying for HIV tests and other health commodities.

DELIVER

John Snow, Inc.

1616 North Fort Myer Drive, 11th Floor

Arlington, VA 22209 USA

Phone: 703-528-7474

Fax: 703-528-7480

Email: deliver_project@jsi.com

Internet: deliver.jsi.com

Contents

Acknowledgements	5
1. Introduction	7
A. Expansion of HIV/AIDS Programs	7
B. Why HIV Tests?	7
2. Background	9
A. Types of HIV Tests	9
B. Primary Uses of HIV Tests	10
C. HIV Testing Protocols	11
3. Quantification	13
A. Define the Program	13
B. Collect Required Data	16
C. Forecast Adjusted Demand	17
D. Estimate Quantities Required	29
E. Calculate Financial Requirements	30
F. Reconcile Available Funding and Quantities Required	31
G. Present Findings to Decision Makers	32
4. Automating Quantification	33
5. End Notes and References	35
6. Appendix: Methodologies	37

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- Medical Stores Department (MSD)
- Pharmacy Board
- MOH, Directorate of Preventative Services
- MOH, National AIDS Control Program (NACP)
- MOH, Diagnostic Services
- Muhimbili University College of Microbiology/Health Sciences
- African Medical and Research Foundation (AMREF)
- Japanese International Cooperating Agency (JICA/MOH)

Kenya

- Office of the President, National AIDS Coordinating Council (NACC)
- Ministry of Health (MOH), Division of HIV/AIDS, Tuberculosis and Leprosy
- MOH, Division of Diagnosis and Forensic Services
- MOH Field Units
- Kenya Medical Supplies Agency (KEMSA)
- Family Planning Association of Kenya (FPAK)
- Marie Stopes Kenya (MSK)
- Family Health International (FHI)
- Crown Agents
- Africa Medical Research Foundation (AMREF)
- Mission for Essential Drugs and Supplies (MEDS)
- U.S. Agency for International Development (USAID)
- Japan International Cooperation Agency (JICA)
- GTZ
- U.S. Centers for Disease Control and Prevention

Uganda

- AIDS Information Centre (AIC)
- Uganda AIDS/HIV Integrated Model District Programme (AIM)
- CDC/Uganda
- Crown Agents
- DDHS Pallisa District
- Uganda Health Sector Strategic Plan (UHSSP)
- Joint Medical Stores (JMS)
- Makasero Blood Transfusion Unit
- MOH, Infection Control
- MOH, Malaria Program
- MOH, Pharmacy
- MOH, STD/ACP
- MOH, TB/Leprosy
- National Medical Store (NMS)
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1. Introduction

A. Expansion of HIV/AIDS Programs

Many countries in the developing world are expanding the range and quality of HIV/AIDS prevention, care, support, and treatment interventions in order to contain and reduce the spread of the epidemic. To facilitate the expansion of services, governments, donors, and other development partners are dedicating a greater proportion of development resources to scale-up HIV/AIDS-related interventions. The Global Fund for AIDS, Tuberculosis and Malaria (GFATM), the World Bank Multi-Sectoral AIDS Project (MAP) initiative, the U.S. Centers for Disease Control and Prevention Global AIDS Program (CDC/GAP), and the U.S. Agency for International Development (USAID) IMPACT project are examples of new, significant resource pools available to HIV/AIDS programs.

The range and quality of services being offered are dependent in part on the availability of HIV/AIDS commodities. The full range of commodities consists of more than 120 products, including—

- condoms for STI/HIV prevention
- essential drugs for treatment of sexually transmitted infection (STI)
- HIV tests
- essential drugs for opportunistic infection (OI) and palliative care
- antiretroviral drugs
- contraceptives.

With the increased volume of commodities, and the need to ensure a consistent and reliable supply to customers, successful programs must be able to—

- Quantify their commodity needs.
- Obligate or orchestrate resources to procure commodities.
- Access skilled personnel to procure these commodities.
- Deliver the commodities reliably to all customers at every service delivery point.

Government and nongovernmental (NGO) HIV/AIDS control program staff may have only recently begun to acquire the skills needed to accurately quantify their HIV commodity needs. To date, many HIV/AIDS interventions are small-scale pilot interventions that work well because a large number of human and financial resources are focused on a small audience. Quantification of the commodity needs and management of the supply chain for small programs is relatively uncomplicated. Replicating these activities on a national scale with proportionally fewer resources, however, poses a major challenge for country programs and donors.

B. Why HIV Tests?

Many countries are already facing this challenge as they begin to estimate national requirements for HIV tests. Rapid HIV test devices and other HIV tests are relatively new to commodity management portfolios. In addition, HIV test technology is evolving rapidly, with new tests being developed and a wide array of test brands already available on the international market. Unlike essential drugs, many countries do not have a national list to control the import of HIV tests. The World Health Organization (WHO) recommends a short list of tests. Having fewer brands facilitates quality assurance, supply management of HIV tests, and training of providers in the use of HIV tests.

This guide presents a process for quantifying HIV test requirements in developing country settings using a variety of forecasting methodologies. It is intended to help program managers and logistics advisors select recognized methodologies and apply them based on specific country circumstances.

These circumstances may include—

- epidemiological profile/disease prevalence
- capacity of the logistics system, service provision system, and human resources
- program maturity
- political will
- financial resource constraints.

This guide does not cover the quantification of the supplies and disposable items that are required for some HIV test kits. These items are very specific to the type and brand of kit chosen. Additionally, an increasing number of newly developed HIV rapid test kits are self-contained and do not require additional supplies.

This guide does not cover the selection, procurement, storage, distribution, and end use of HIV tests.

2. Background

Prior to quantifying HIV test requirements, it is important to have a basic knowledge of HIV tests and HIV testing.

A. Types of HIV Tests

Currently, there are more than 70 brands of HIV tests, and the technology is evolving rapidly. In the next few years, many new tests will likely replace current ones. The majority of HIV tests being used in developing country settings fall into one of the three basic groups shown in table 1.

Table 1. HIV Tests

Test	Site of Use	Advantages	Limitations	Cost
Simple/rapid assay (Rapid test device or RTD)	Small labs, VCT sites, PMTCT sites, STD and TB clinics, emergency care centers.	<ul style="list-style-type: none"> Easy to use and interpret test results. Results within 10–30 minutes. No minimum volume of tests required. Requires minimal equipment. Does not require highly skilled staff. Many newer tests can be stored at room temperature. When used in combination, results as reliable as ELISAs. Can be used on various types of specimens, including whole blood. Oral fluid tests have been developed recently, are non-invasive, and do not require sharps. Can be used to do on-site/point of care testing. 	<ul style="list-style-type: none"> Small-scale testing. Considerable variation in sensitivity. However, this often depends on type of specimen (i.e., whole blood, serum, oral fluid). Cold chain sometimes required. May cost more per individual test. Some products are less sensitive for seroconvertors. Using rapid tests at multiple sites in resource poor countries poses quality assurance challenges. 	Relatively expensive.
ELISA	Large hospitals, blood banks, or reference laboratories.	<ul style="list-style-type: none"> Highly sensitive, especially for picking up seroconvertors. Batch testing. Can be automated. Easier to conduct quality assurance testing, because tests are performed in fewer, high-volume laboratories. 	<ul style="list-style-type: none"> Requires more time to obtain results (1–3 hours) and even longer if not at point of care. Need sophisticated equipment and equipment maintenance. Cold chain always required. Need minimum volume of tests for maximum efficiency. Requires skilled technicians. 	Relatively more expensive than rapid test device, but cost-effective with large batches. Can be expensive if only used for small batches.
Western blot	Large teaching hospitals, reference laboratories, and National Reference Laboratory.	<ul style="list-style-type: none"> The “Gold Standard.” Detects all antibodies present. 	<ul style="list-style-type: none"> Requires skilled and experienced personnel. Non-routine test (small batches only, usually < 10) used for research and clarifying indeterminate results. 	Very expensive.

Rapid Test Devices (RTDs) are also ELISAs, but are listed as a separate type because of the nearly immediate results provided and because of other characteristics of the tests. Traditional ELISAs are sometimes referred to as long ELISAs because they take up to three hours to produce a test result.

B. Primary Uses of HIV Tests

- ***Ensuring Blood Safety:*** Testing blood and blood products for HIV and other infectious diseases is a relatively simple intervention that prevents disease transmission through transfusion. Testing for HIV and other infectious diseases allows for infected or suspect blood to be discarded or destroyed, thereby ensuring the safety of the blood supply. WHO's Global Database on Blood Safety, however, indicates that 80 percent of the world's population does not have access to safe and reliable blood (WHO 2001). High rates of HIV and hepatitis infection among donors in some countries make blood transfusions a serious risk. WHO reports that unsafe blood products cause 5–10 percent of new HIV infections. In some blood safety programs, blood donors are informed of their sero-status (linked testing). In other programs, the donors are not informed of the results of testing (unlinked testing).
- ***Voluntary Counseling and Testing (VCT):*** Voluntary HIV counseling and testing (VCT) is now acknowledged as a pivotal strategy for HIV/AIDS prevention, care, support, and treatment activities. Individuals who test negative can take appropriate measures to avoid becoming infected. Individuals who test positive can access treatment, care, and support services, including condom distribution, PMTCT, prevention, and clinical management of HIV-related illnesses, STI and tuberculosis control, psychosocial and legal support, and antiretroviral therapy, if available. In VCT, the speed of the test is critical, because it is important to give the client the test result during the visit. In most settings some percentage of clients will not make a return visit even if asked. In these cases, the opportunity to give the test result and to counsel based on the result, will be lost.¹
- ***Prevention of Mother-to-Child Transmission (PMTCT):*** HIV testing of pregnant women allows them to learn their own sero-status. Women who test positive can take appropriate steps to reduce the probability of passing HIV to their child during childbirth and breastfeeding. Without intervention, there is a 15–30 percent risk of MTCT during pregnancy and delivery, and an additional 10–20 percent risk through breastfeeding. In some countries, HIV testing for PMTCT is voluntary. In these cases, the percentage of pregnant women who seek testing must be considered as part of the quantification formula. In other countries, testing is mandatory, and the number of pregnant women tested will be 100 percent of antenatal care clinic attendance. PMTCT testing programs should have pre-testing and post-testing counseling components.
- ***Testing of HIV-Exposed Babies (Department of Health, Cape Town 2002):*** All babies born to HIV-positive mothers are HIV-exposed. All HIV-exposed babies should be HIV tested at nine months of age using rapid HIV tests. The nine-month age is chosen for the HIV testing because it can be coordinated with the nine months of age immunization visit. At nine months, or at any age, an HIV-negative test means the baby is uninfected, unless the baby is being breastfed. Breastfed babies can contract HIV infection from breast milk. All breastfed babies, even if testing HIV-negative at nine or 18 months,

should be retested three months after weaning from breast milk in those cases where breastfeeding continues for longer than 4–6 months. Babies testing HIV-positive at nine months should be retested at 18 months. The 18-month retesting is necessary because some babies who test positive at nine months are actually false positives because they are slow in clearing their maternal HIV antibodies. An HIV-positive test at 18 months or older confirms HIV infection in an HIV-exposed baby.

- **Clinical Diagnosis:** HIV testing is conducted when an inpatient or outpatient shows signs and symptoms of AIDS, when health workers and care providers suffer needle stick or exposure to bodily fluids of a known HIV-positive person (post-exposure prophylaxis), and when a person is a victim of sexual assault. Individuals requiring a certificate of HIV sero-status for employment, marriage, schooling, visas, etc., might also be tested in a clinical setting.

Because of the varied circumstances under which HIV tests are given for clinical diagnosis, it can be difficult to conduct quantification. In some cases, there may be no separate clinical diagnosis program and no separate HIV test procurement activity for diagnostic testing. In these cases, there may not be defined testing protocols. If so, the protocols used are likely to vary considerably, complicating the quantification calculations. Data for quantification in these situations is likely to be difficult to obtain as well, because most health management information systems (HMIS) and periodic surveys do not capture the required information. In spite of these difficulties, the use of HIV tests for clinical diagnosis must be considered in quantifying HIV test requirements. If not, HIV tests intended for blood safety or other uses may be diverted for diagnostic testing, resulting in a shortage of tests for the intended purpose.

- **Sentinel Surveillance (SS):** HIV testing is conducted on select population subgroups to enable health officials to describe the HIV/AIDS epidemic in a country, to plan and advocate for responses, and to evaluate the effectiveness of the responses. “Countries with generalized epidemics conduct sero-surveillance primarily among pregnant women at antenatal clinics as the basis of their surveillance system. Countries with concentrated epidemics or low-level epidemics focus primarily on specific population groups that are perceived to be at high risk for infection, for example, female sex workers and their clients, injecting drug users, or men who have sex with men.” (WHO 2001)

Sentinel surveillance testing can be linked, i.e., the people tested are informed of the results, or it can be unlinked, i.e., the people tested are not informed of the test results.

- **Other Uses:** This category includes training and special studies, e.g., Demographic and Health Survey (DHS). It could also include large scale institutional testing of special populations such as military, police, prisoners, etc., who may not necessarily go to traditional VCT or clinical sites.

C. HIV Testing Protocols

Most established HIV/AIDS programs have defined testing protocols or algorithms for each of the primary uses of HIV tests. The testing protocols are a guide for the individuals administering the tests. The protocols vary based on HIV prevalence, the purpose of the testing, and the number of different tests available in the program. Testing may be serial or parallel, and this also depends on HIV prevalence, purpose of testing, and availability of tests.

The following are examples of testing protocols:

Serial Protocols

Protocol S1	Protocol S2	Protocol S3
A	A B	A B C
<p>If positive, result is positive.</p> <p>If negative, result is negative.</p>	<p>If test A positive, run test B. If test B positive, result is positive.</p> <p>If test B negative, results inconclusive.</p> <p>If test A negative, result is negative.</p>	<p>If test A positive, run test B. If test B positive, result is positive.</p> <p>If test B negative, run test C. If test C is positive, result is positive.</p> <p>If test C is negative, result is negative.</p> <p>If test A negative, result is negative.</p>

S = serial testing **P** = parallel testing

If protocol S3 above, or protocols P1, P3, or P4 below are being used in the program, the person doing the quantification must determine the average discordance rate between all brands of Test A and all brands of Test B. In addition, if Protocol P4 is being used, the person conducting the quantification must determine the average discordance between all brands of Test C and all brands of Test D. These discordance rates become the basis for determining the number of tie-breaker tests required.

Parallel Protocols

Protocol P1	Protocol P2	Protocol P3	Protocol P4
AB C	A BC	AB CD	AB CD E
<p>Tests A and B run in parallel. If tests A and B both negative, result is negative.</p> <p>If tests A and B both positive, result is positive.</p> <p>If tests A and B discordant, run test C.</p> <p>If test C positive, result is positive.</p>	<p>If test A negative, result is negative.</p> <p>If test A positive, run tests B and C in parallel. If one or both of tests B and C, positive, result is positive.</p> <p>If tests B and C both negative, result is negative.</p>	<p>Tests A and B run in parallel. If tests A and B both negative, result is negative.</p> <p>If tests A and B both positive, result is positive.</p> <p>If tests A and B discordant, run tests C and D in parallel.</p> <p>If tests C and D both negative, result is negative.</p> <p>If tests C and D both positive, result is positive.</p> <p>If tests C and D discordant, run test E.</p> <p>If test E positive, result is positive.</p> <p>If test E negative, result is negative.</p>	<p>Tests A and B run in parallel. If tests A and B both negative, result is negative.</p> <p>If tests A and B both positive, result is positive.</p> <p>If tests A and B discordant, run tests C and D in parallel.</p> <p>If tests C and D both negative, result is negative.</p> <p>If tests C and D both positive, result is positive.</p> <p>If tests C and D discordant, run test E.</p> <p>If test E positive, result is positive.</p> <p>If test E negative, result is negative.</p>

3. Quantification

Quantification is the general term for the process of estimating the quantities of specific drugs, laboratory reagents, and consumable medical supplies required to serve customers in a health program for a given period of time. Quantification is accomplished in the following eight steps or stages:

1. Define the program you are quantifying.
2. Collect the data required to complete all remaining steps.
3. Forecast demand and adjust for quality control, wastage, and service capacity.
4. Estimate quantities required.
5. Calculate financial requirements.
6. Reconcile available funding and quantities required.
7. Present findings to decision makers to determine quantities to procure.
8. Update and revise the quantification as new, more accurate data becomes available.

This quantification guide presents the process for completing each of the stages when quantifying for HIV test requirements.

A. Define the Program

Before beginning the actual HIV test requirements quantification, it is important to clearly define the program(s) you are quantifying.

From a logistics perspective, a *program* is all the HIV testing activities that have a common distribution pipeline. The HIV tests can be provided from the same funding source or from different funding sources, but, if they all go into the same distribution pipeline, this is considered one program and requires one quantification.

Conversely, the test kits can be provided from one funding source or from separate funding sources, but if they are distributed through separate distribution pipelines, e.g., the MOH distribution system and the Mission sector distribution system, each of these pipelines is considered a different program. Quantification must be conducted for each program.

Example 1. In Country X the funds for test kits for blood safety are provided by the government, the funds for test kits for VCT and PMTCT are provided by the European Union, and the funds for test kits for sentinel surveillance are provided by the Centers for Disease Control and Prevention (CDC). However, all the kits are stored and distributed under the MOH system for HIV/AIDS-related products. In this case, you would quantify for each of these four purposes and then aggregate the quantities required to determine the total quantities of kits required by the MOH.

Example 2. In Country Y, you are asked to conduct quantification for the blood safety, VCT, and sentinel surveillance activities. As you begin your questioning you discover that the VCT and sentinel surveillance program HIV tests are procured through the MOH Public Health Unit and MOH Logistics Unit, and are distributed through the MOH regular essential drugs distribution system. The tests for blood safety are donated by an NGO, briefly stored, and then distributed separately to the government blood collection sites by a private distributor under contract to the NGO. These are two separate programs, and would require separate quantification exercises.

If there is no program to supply HIV tests for a certain purpose, e.g., clinical diagnosis, the “wastage” factor for the other purposes might have to be increased. This is because tests intended for uses such as blood safety or sentinel surveillance might be diverted to testing for clinical diagnosis, VCT, or PMTCT.

In addition to knowing the uses for HIV tests in the program, it is also necessary to gather information about how the testing services for various uses are structured. This will allow the quantifier to ask the right questions for each use and to review the correct records and reports.

Questions that will provide general background information for defining the program include the following:

BLOOD SAFETY

1. Is the testing protocol for blood safety the same throughout the country?
2. Is the testing protocol for blood safety the same in the government, NGO, missionary, and private facilities?
3. Is the blood safety program centralized or decentralized?
4. How many sites collect donated blood?
5. Is blood collected at the transfusion site or elsewhere?
6. Where is blood tested: at collection site, blood bank, or transfusion site?
7. How many laboratories do blood screening?
8. Are there NGO, missionary, or private suppliers/testers of blood?
If yes, who supplies their HIV tests?
9. What brands and types of tests are used at what level in the program?

VCT

1. Is the testing protocol for VCT the same throughout the country?
2. Is the testing protocol for VCT the same in the government, NGO, missionary, and private facilities?
3. Is the VCT program centralized or decentralized?
4. How many VCT sites are there (sites with trained counselor and testing capacity)?
5. How many of these are government, NGO, and mission sector sites?
6. Where is blood tested: at the VCT site or elsewhere?
7. Where are the VCT sites located?
8. Are there plans to open new VCT sites in the future? If yes, how many?
9. From where do the NGO and mission sector VCT sites receive their HIV tests?
10. What brands and types of HIV tests are used at what levels in the program?

PMTCT

1. Is the testing protocol for PMTCT the same throughout the country?
2. Is the testing protocol for PMTCT the same in the government, NGO, missionary, and private facilities?
3. Is the PMTCT program centralized or decentralized?

4. How many PMTCT sites are there?
5. How many of these are government, NGO, and mission sector sites?
6. Where is blood tested: at the PMTCT site or elsewhere?
7. Where are the PMTCT sites located?
8. Are there plans to open new PMTCT sites in the future? If so, how many?
9. From where do the NGO and mission sector sites receive their HIV tests?
10. What brands and types of HIV tests are used at what levels in the program?

TESTING OF HIV-EXPOSED BABIES

1. Is the testing protocol for HIV-exposed babies the same throughout the country?
2. Is the testing protocol for HIV-exposed babies the same in the government, NGO, missionary, and private facilities?
3. Is the HIV-exposed babies testing program centralized or decentralized?
4. Are HIV-exposed babies tested at antenatal care (ANC) sites or at other health facilities?
5. How many testing sites are there for HIV-exposed babies?
6. How many of these are government, NGO, and mission sector sites?
7. Where is blood tested: at the HIV-exposed babies testing site or elsewhere?
8. Where are the HIV-exposed babies testing sites located?
9. Are there plans to open new sites for testing HIV-exposed babies in the future? If so, how many?
10. From where do the NGO and mission sector sites receive their HIV tests?
11. What brands and types of HIV tests are used at what levels in the program?

CLINICAL DIAGNOSIS

1. Are AIDS patients routinely diagnosed through clinical diagnosis?
2. What service statistics are available on the use of HIV tests for clinical diagnosis?
3. Approximately how many and what types of sites conduct HIV testing for clinical diagnosis?
4. What consumption data is available for HIV tests for clinical diagnosis?
5. Is the testing protocol for clinical diagnosis the same throughout the country?
6. Is the testing protocol for clinical diagnosis the same in government, NGO, missionary, and private facilities?
7. From where do the NGO and mission sector sites receive their HIV tests for clinical diagnosis?
8. What brands and types of HIV tests are used at what levels in the program for clinical diagnosis?

SENTINEL SURVEILLANCE

1. How many sentinel surveillance sites are there and of what type?
2. What is the sample size per sentinel surveillance site?
3. Where are sentinel surveillance site blood samples tested?

4. Is sentinel surveillance an ongoing, year-round activity, or is it for a limited time each year?
5. What brands and types of HIV tests are used for sentinel surveillance?

In defining the program(s), it is important to develop an HIV test flow map for each program that shows the suppliers (funding sources) of the test kits, products supplied, products supplied for which uses, and the general distribution flow of the kits from suppliers to points of use. Carefully defining the program will help avoid double-counting of some HIV test requirements and failing to count other HIV test requirements.

B. Collect Required Data

It was mentioned earlier that HIV tests have seven uses—blood safety, VCT, PMTCT, testing HIV-exposed babies, sentinel surveillance, clinical diagnosis, and others (training and special studies). Once you have determined the uses for HIV tests in the program you are quantifying and how the HIV testing services for the various uses are structured, you must gather the data needed to estimate the quantities required for each of these uses.

The likely sources for much of the data needed for HIV test requirements quantification are key informants and program documents in-country.

Key informants to interview include—

- head of the national laboratory services
- head of blood safety/transfusion services
- head of the national AIDS control program (NACP)
(usually within the Ministry of Health)
- head of the National AIDS Committee (NAC)
(usually a multisectoral committee within the office of the president or head of state)
- head of national hospital services
- heads of tertiary care hospitals
- heads of local blood collection facilities (in decentralized environment)
- heads of NGOs conducting HIV tests
- donors involved in HIV/AIDS support
- procurement agents
- VCT, sentinel surveillance, blood collection/transfusion, and MTCT program field units
- private sector suppliers and testers of blood.

Program documents that are likely to provide useful information include—

- national HIV/AIDS/STI policy papers
- MOH annual reports
- MOH list of sites collecting/transfusing blood
- reports from local blood testing facilities
- AIDS commission reports
- NACP annual reports
- NACP project plans
- NACP VCT plans and reports

- NACP sentinel surveillance plans and reports
- budgetary documents or proposals
- Demographic and Health Surveys
- national essential drugs list, particularly for laboratory reagents, supplies, and materials
- HIV testing protocols
- standard treatment guidelines
- health management information system (HMIS) reports
- logistics records and reports on HIV test kit procurement, distribution, consumption, and balances
- special reports, studies from other cooperating agencies and donors, e.g., FHI, PSI, JHU/PCS, CDC, GTZ, DFID, etc.

See the reference section at the end of this paper for other HIV test kit quantification data sources.

Collecting the data required to complete the quantification will probably be the most time consuming and difficult of all the steps in the quantification process. In many cases, the required data may not be available. To proceed with the quantification in cases where key data are not available or are of very poor quality, it may be necessary to make estimates based on information gathered from key informants.

C. Forecast Adjusted Demand

In this step of the quantification process, you forecast demand and then adjust for quality control, wastage, and service capacity. The resulting figure is the adjusted demand. Tables 2–8 present the information that must be collected for forecasting adjusted demand for each of the six uses of HIV tests.

There are four recognized methodologies that can be used to forecast demand for HIV tests. The appendix at the end of this guide explains the four methodologies and how to apply them to each of the uses for HIV tests. See the methodologies pages in the appendix for help as you work through tables 2–8.

After you have defined the program and gathered the information in tables 2–8, you can forecast adjusted demand.

Remember that you will be forecasting individual HIV tests (to test one sample). All of the calculations in this document use individual tests as the unit, until the very end of the process when the numbers of tests will be converted into the numbers of kits.

Forecast Demand

It is highly recommended that more than one of the four available methodologies be used for forecasting demand for each use of HIV tests. The results obtained should then be compared and reconciled by program managers.

Table 2. Data Required to Forecast Adjusted Demand for HIV Tests for Blood Safety

DEMAND			
Logistics	Demographic/Morbidity	Service Statistics	Target
<ol style="list-style-type: none"> 1. How many of each brand of tests were consumed the past year³ for blood safety? 2. What is the lowest level of the system having relatively complete data? 3. For this level of the logistic system, what was the beginning inventory of each brand of test at the start of the year?⁴ 4. For this level of the logistic system, what were the receipts for each brand of test for the year? 5. For this level of the logistic system, what were the expiries, losses, and adjustments for each brand of test for the year? 6. For this level of the logistic system, what was the ending inventory for the year? 7. What is the expected rate of change of HIV test consumption for blood safety for the year for which you are quantifying? 	<ol style="list-style-type: none"> 1. What is the population of the catchment area covered by this blood safety program? 2. What percentage of people in this population will donate blood? 3. On average, how many times does a blood donor donate per year? 4. What is the HIV prevalence rate among blood donors?³ 5. What is the average discordance rate between the screening and confirmatory tests? 6. What is the HIV testing protocol for blood safety? 	<ol style="list-style-type: none"> 1. How many blood units were collected during the past year?³ 2. How many blood units were transfused during the past year? 3. What percentage of blood units collected during the past year was discarded (include blood units discarded for testing positive for pathogens, expiry, and other reasons)? 4. What is the expected rate of change in blood collection in the year for which you are quantifying? 5. What is the HIV prevalence rate among blood donors?⁵ 6. What is the average discordance rate between the screening and confirmatory tests? 7. What is the HIV testing protocol for blood safety? 	<ol style="list-style-type: none"> 1. What is the targeted number of blood units to be collected in the year for which you are quantifying? 2. What is the HIV prevalence rate among blood donors?⁵ 3. What is the average discordance rate between the screening and confirmatory tests? 4. What is the HIV testing protocol for blood safety?
Quality Control and Wastage Factors			
<ol style="list-style-type: none"> 1. What percentage of each brand of test will be used for quality control purposes? 2. What percentage of each brand of test will be wasted through expiry, faulty product, etc.? 			
Service Capacity			
<ol style="list-style-type: none"> 1. For blood safety, what is the total number of technicians conducting HIV tests? 2. How many days a year, on average, will a technician conduct HIV tests for blood safety? 3. On average, how many HIV tests for blood safety will a technician conduct per day? 4. If reliable service capacity data is not available, discuss with key informants the testing capacity for blood safety. Using this information, determine the maximum number of tests that can be conducted for purposes of blood safety during the year for which you are quantifying. <p>If an ELISA/Blot is picked for the test selection—</p> <ol style="list-style-type: none"> 5. What is the yearly laboratory machine capacity for conducting the HIV test indicated in the product selection? 			

Table 3. Data Required to Forecast Adjusted Demand for HIV Tests for Voluntary Counseling and Testing (VCT)

DEMAND			
Logistics	Demographic/Morbidity	Service Statistics	Target
<ol style="list-style-type: none"> 1. How many of each brand of tests were consumed for VCT in the past year?³ 2. What is the lowest level of the system having relatively complete data? 3. For this level of the logistic system, what was the beginning inventory for each brand of test at the start of the year?⁴ 4. For this level of the logistic system, what were the receipts for each brand of test for the year? 5. For this level of the logistic system, what were the expiries, losses, and adjustments for each brand of test for the year? 6. For this level of the logistic system, what was the ending inventory for each brand of test for the year? 7. What is the expected rate of change of HIV test consumption for VCT in the year you are quantifying? 	<ol style="list-style-type: none"> 1. What is the total population of the catchment areas served by VCT sites? 2. What percentage of the population in the catchment areas served by VCT sites is likely to come for counseling? 3. What percentage of counseled clients is likely to request an HIV test? 4. What is the HIV prevalence rate of VCT clients requesting an HIV test? 5. What is the average discordance rate between the screening and confirmatory tests? 6. What is the testing protocol for VCT? 	<ol style="list-style-type: none"> 1. For VCT, how many clients were tested during the past year?³ 2. What is the HIV prevalence rate among the tested clients? 3. What is the expected rate of change for VCT? 4. What is the average discordance rate between the screening and confirmatory tests? 5. What is the testing protocol for VCT? 	<ol style="list-style-type: none"> 1. What is the targeted number of VCT clients to be tested in the year you are quantifying? 2. What is the HIV prevalence rate among VCT clients? 3. What is the average discordance rate between the screening and confirmatory tests? 4. What is the testing protocol for VCT?
Quality Control and Wastage Factors			
<ol style="list-style-type: none"> 1. What percentage of each brand of test will be used for quality control purposes? 2. What percentage of each brand of test will be wasted through expiry, faulty product, etc.? 			

Service Capacity

1. For the VCT program, what is the total number of counselors?
2. How many days a year, on average, will a counselor do VCT?
3. Do counselors conduct HIV tests? **YES** ☐ **NO** ☐

If YES, proceed to question #4A. If NO, proceed to question #4B.

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| <p>4A. On average, how many VCT clients per day will a counselor counsel if this same counselor is also conducting the tests?</p> <p>5A. What percentage of counseled clients is likely to request HIV testing?</p> <p>- OR -</p> <p>6A. If reliable service capacity data is not available, discuss with key informants the counseling and testing capacity for VCT. Using this information, determine the maximum number of clients who can be tested in the VCT program during the year you are quantifying.</p> | <p>4B. On average, how many VCT clients per day will a counselor counsel if the counselor is not conducting the tests?</p> <p>5B. What percentage of counseled clients are likely to request HIV testing?</p> <p>6B. For the VCT program, what is the total number of technicians conducting HIV tests?</p> <p>7B. How many days a year, on average, will a technician conduct HIV tests for VCT?</p> <p>8B. On average, how many HIV tests for VCT will a technician conduct per day?</p> <p>- OR -</p> <p>9B. If reliable service capacity data is not available, discuss with key informants the testing capacity for VCT. Using this information, determine maximum number of clients who can be tested in the VCT program during the year you are quantifying.</p> <p>If an ELISA/Blot is picked for the test kit selection —</p> <p>10B. What is the yearly laboratory machine capacity for conducting the HIV test indicated in the product selection for VCT?</p> |
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Table 4. Data Required to Forecast Adjusted Demand for HIV Tests for Prevention of Mother-to-Child Transmission (PMTCT)

DEMAND			
Logistics	Demographic/Morbidity	Service Statistics	Target
<ol style="list-style-type: none"> 1. How many of each brand of tests were consumed during the past year³ for PMTCT? 2. What is the lowest level of the system having relatively complete data? 3. For this level of the logistic system, what was the beginning inventory for each brand of test at the start of the year?⁴ 4. For this level of the logistic system, what were the receipts for each brand of test for the year?⁴ 5. For this level of the logistic system, what were the expiries, losses, and adjustments for each brand of test for the year? 6. For this level of the logistic system, what was the ending inventory for each brand of test for the year? 7. What is the expected rate of change of HIV test consumption for PMTCT? 	<ol style="list-style-type: none"> 1. How many women of reproductive age live in the catchment area of ANC sites offering PMTCT? 2. What is the pregnancy rate in the catchment area? 3. What percentage of pregnant women in the catchment areas will make at least one ANC visit? 4. What percentage of these ANC clients is likely to request counseling for HIV? 5. What percentage of ANC clients counseled is likely to request an HIV test? 6. What is the HIV prevalence rate among PMTCT clients? 7. What is the average discordance rate between the screening and confirmatory tests? 8. What is the testing protocol for PMTCT? 	<ol style="list-style-type: none"> 1. How many pregnant women were tested for HIV in sites offering PMTCT in the past year?³ 2. What is the HIV prevalence rate among pregnant women tested at PMTCT sites in the past year? 3. What is the average discordance rate between the screening and confirmatory tests? 4. What is the expected rate of change for PMTCT testing? 5. What is the testing protocol for PMTCT? 	<ol style="list-style-type: none"> 1. What is the targeted number of clients to be tested for PMTCT in the year you are quantifying? 2. What is the HIV prevalence rate among PMTCT clients? 3. What is the average discordance rate between the screening and confirmatory tests? 4. What is the testing protocol for PMTCT?
Quality Control and Wastage Factors			
<ol style="list-style-type: none"> 1. What percentage of each brand of test will be used for quality control purposes? 2. What percentage of each brand of test will be wasted through expiry, faulty product, etc.? 			

Service Capacity

1. For the PMTCT program, what is the total number of counselors?
2. How many days a year, on average, will a counselor do PMTCT?
3. Do counselors themselves conduct HIV tests? **YES** ☐ **NO** ☐
4. If YES, proceed to question #4A. If NO, proceed to question #4B.

(Continue with question 4A or 4B on the next page)

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| <p>4A. On average, how many PMTCT clients per day will a counselor counsel if this same counselor is also conducting the tests?</p> <p>5A. What percentage of counseled clients is likely to request HIV testing?</p> <p>- OR -</p> <p>6A. If reliable service capacity data is not available, discuss with key informants the counseling and testing capacity for PMTCT. Using this information, determine the maximum number of clients who can be tested in the program for the testing of HIV-exposed babies during the year you are quantifying.</p> | <p>4B. On average, how many PMTCT clients per day will a counselor counsel?</p> <p>5B. What percentage of counseled clients is likely to request HIV testing?</p> <p>6B. For the PMTCT program, what is the total number of technicians conducting HIV tests?</p> <p>7B. How many days a year, on average, will a technician conduct HIV tests for PMTCT?</p> <p>8B. On average, how many HIV tests for PMTCT will a technician conduct per day?</p> <p>- OR -</p> <p>9B. If reliable service capacity data is not available, discuss with key informants the testing capacity for PMTCT. Using this information, determine the maximum number of clients who can be tested in the program for the testing of HIV-exposed babies during the year you are quantifying.</p> <p>If an ELISA/Blot is picked for the test kit selection—</p> <p>10B. What is the yearly laboratory machine capacity for conducting the HIV test indicated in the product selection for PMTCT?</p> |
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Table 5. Data Required to Forecast Adjusted Demand for HIV Tests for Testing HIV-Exposed Babies

DEMAND			
Logistics	Demographic/Morbidity	Service Statistics	Target
<ol style="list-style-type: none"> 1. How many of each brand of tests were consumed during the past year³ for testing HIV-exposed babies? 2. What is the lowest level of the system having relatively complete data? 3. For this level of the logistic system, what was the beginning inventory for each brand of test at the start of the year?⁴ 4. For this level of the logistic system, what were the receipts for each brand of test for the year? 5. For this level of the logistic system, what were the expiries, losses, and adjustments for each brand of test for the year? 6. For this level of the logistic system, what was the ending inventory for each brand of test for the year? 7. What is the expected rate of change of HIV test consumption for testing HIV-exposed babies? 	<ol style="list-style-type: none"> 1. What percentage of babies of HIV-positive PMTCT clients will be brought for HIV testing at age 9 months? 2. What is the percentage of HIV-exposed babies who test HIV-negative at age 9 months? 3. What percentage of HIV-negative babies at age 9 months will still be breastfeeding? 4. What percentage of HIV-negative babies still breastfeeding at 9 months will be brought for retesting 3 months after being weaned from breast milk? 5. What percentage of HIV-exposed babies test HIV-positive at age 9 months? 6. What percentage of HIV-positive babies at age 9 months will be brought for retesting at age 18 months? 7. What percentage of HIV-negative babies at age 18 months will still be breastfeeding? 8. What percentage of HIV-negative babies still breastfeeding at 18 months will be brought for retesting 3 months after being weaned from breast milk? 9. What is the average discordance rate between the screening and confirmatory tests? 10. What is the testing protocol for testing HIV-exposed babies? 	<ol style="list-style-type: none"> 1. How many HIV-exposed babies were tested in the ANC sites offering PMTCT during the previous year?³ 2. What was the HIV prevalence rate among HIV-exposed babies tested at ANC clinics? 3. What is the average discordance rate between the screening and confirmatory tests? 4. What is the expected rate of change for testing HIV-exposed babies? 5. What is the testing protocol for testing HIV-exposed babies? 	<ol style="list-style-type: none"> 1. What is the targeted number of HIV-exposed babies to be tested in the year you are quantifying? 2. What is the HIV prevalence rate among HIV-exposed babies? 3. What is the average discordance rate between the screening and confirmatory tests? 4. What is the testing protocol for testing HIV-exposed babies?
Quality Control and Wastage Factors			
<ol style="list-style-type: none"> 1. What percentage of each brand of test will be used for quality control purposes? 2. What percentage of each brand of test will be wasted through expiry, faulty product, etc.? 			

Service Capacity

1. In the program for testing of HIV-exposed babies, what is the total number of counselors?
2. How many days a year, on average, will a counselor counsel caregivers of HIV-exposed babies?
3. Do counselors conduct HIV tests? YES ☐ NO ☐

If YES, proceed to question #4A. If NO, proceed to question #4B.

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| <p>4A. On average, how many caregivers of HIV-exposed babies will a counselor counsel per day if this same counselor is also conducting the tests?</p> <p>5A. If reliable service capacity data is not available, discuss with key informants the counseling and testing capacity for testing HIV-exposed babies. Using this information, determine the maximum number of clients who can be tested in the PMTCT program during the year you are quantifying.</p> <p>4B. On average, how many caregivers of HIV-exposed babies will a counselor counsel per day if the counselors are not conducting the tests?</p> | <p>5B. For the testing of HIV-exposed babies program, what is the total number of technicians conducting HIV tests?</p> <p>6B. How many days a year, on average, will a technician conduct HIV tests for the testing of HIV-exposed babies program?</p> <p>7B. On average, how many HIV tests for the testing of HIV-exposed babies will a technician conduct per day?</p> <p>8B. If reliable service capacity data is not available, discuss with key informants the testing capacity for the testing of HIV-exposed babies program. Using this information, determine the maximum number of clients who can be tested in the PMTCT program during the year you are quantifying.</p> <p>If an ELISA/Blot is picked for the test kit selection—</p> <p>9B. What is the yearly laboratory machine capacity for conducting the HIV test indicated in the product selection for the testing of HIV-exposed babies program?</p> |
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Table 6. Data Required to Forecast Adjusted Demand for HIV Tests for Sentinel Surveillance

DEMAND			
Logistics	Demographic/Morbidity	Service Statistics	Target
N/A	N/A	N/A	<ol style="list-style-type: none"> 1. How many people will be tested for HIV in the sentinel surveillance program in the year you are quantifying? 2. How many or what percentage of the screened specimens will be tested for quality control? 3. What is the average discordance rate between the screening and quality control tests, or what percentage or number of the quality control tests will require validation testing? 4. What is the testing protocol for sentinel surveillance?
Quality Control and Wastage Factors			
<ol style="list-style-type: none"> 1. What percentage of each brand of test will be used for quality control purposes? 2. What percentage of each brand of test will be wasted through expiry, faulty product, etc.? 			
Service Capacity			
<ol style="list-style-type: none"> 1. For sentinel surveillance, what is the total number of technicians conducting HIV tests? 2. How many days a year, on average, will a technician conduct HIV tests for sentinel surveillance? 3. On average, how many HIV tests for sentinel surveillance will a technician conduct per day? - OR - 4. If reliable service capacity data is not available, discuss with key informants the testing capacity for sentinel surveillance. Using this information, determine the maximum number of tests that can be conducted for sentinel surveillance during the year you are quantifying. <p>If an ELISA/Blot is picked for the test kit selection—</p> <ol style="list-style-type: none"> 5. What is the yearly laboratory machine capacity for conducting the HIV test indicated in the product selection? 			

Table 7. Data Required to Forecast Adjusted Demand for HIV Tests for Clinical Diagnosis

DEMAND			
Logistics	Demographic/Morbidity	Service Statistics	Target
<ol style="list-style-type: none"> 1. How many of each brand of tests were consumed in the past year³ for clinical diagnosis? 2. What is the lowest level of the system having relatively complete data? 3. For this level of the logistic system, what was the beginning inventory for each brand of test at the start of the year?⁴ 4. For this level of the logistic system, what were the receipts for each brand of test for the year? 5. For this level of the logistic system, what were the expiries, losses, and adjustments for each brand of test for the year? 6. For this level of the logistic system, what was the ending inventory for each brand of test for the year? 7. What is the expected rate of change of HIV test consumption for clinical diagnosis? 	<ol style="list-style-type: none"> 1. What is the population of the catchment areas of health facilities receiving HIV tests under this program? 2. What percentage of the population in the catchment area will access medical facilities this year? 3. What percentage of individuals accessing medical facilities are tested for HIV? 4. In the catchment areas, what is the AIDS prevalence of the population accessing medical facilities? 5. What is the average discordance rate between the screening and confirmatory tests? 6. What is the testing protocol for clinical diagnosis? 	<ol style="list-style-type: none"> 1. How many HIV tests were conducted in clinical settings during the past year⁵ for diagnostic testing? 2. What is the expected rate of change in HIV testing for clinical diagnosis in the year you are quantifying? 3. How many of the HIV tests conducted in the past year for clinical diagnosis testing were HIV-positive? 4. What is the average discordance rate between the screening and confirmatory tests? 5. What is the testing protocol for clinical diagnosis? 	<ol style="list-style-type: none"> 1. What is the anticipated number of clients to be tested for HIV for reasons of clinical diagnosis in the year you are quantifying? 2. What is the HIV prevalence rate of clients tested for HIV for purposes of clinical diagnosis? 3. What is the average discordance rate between the screening and confirmatory tests? 4. What is the testing protocol for clinical diagnosis?
Quality Control and Wastage Factors			
<ol style="list-style-type: none"> 1. What percentage of each brand of test will be used for quality control purposes? 2. What percentage of each brand of test will be wasted through expiry, faulty product, etc.? 			
Service Capacity			
<ol style="list-style-type: none"> 1. For clinical diagnosis, what is the total number of technicians conducting HIV tests? 2. How many days a year, on average, will a technician conduct HIV tests for clinical diagnosis? 3. On average, how many HIV tests for clinical diagnosis will a technician conduct per day? - OR - 4. If reliable service capacity data is not available, discuss with key informants the testing capacity for clinical diagnosis. Using this information, determine the maximum number of tests that can be conducted for clinical diagnosis during the year you are quantifying. <p>If an ELISA/Blot is picked for the test kit selection—</p> <ol style="list-style-type: none"> 5. What is the yearly laboratory machine capacity for conducting the HIV test indicated in the product selection? 			

Table 8. Data Required to Forecast Adjusted Demand for HIV Tests for Other Uses (Including Training and Research)

DEMAND			
Logistics	Demographic/Morbidity	Service Statistics	Target
<ol style="list-style-type: none"> 1. How many of each brand of tests were consumed during the past year³ for the other use(s) you are quantifying? 2. What is the lowest level of the system having relatively complete data? 3. For this level of the logistic system, what was the beginning inventory for each brand of test at the start of the year?⁴ 4. For this level of the logistic system, what were the receipts for each brand of test for the year? 5. For this level of the logistic system, what were the losses and adjustments for each brand of test for the year? 6. For this level of the logistic system, what was the ending inventory for each brand of test for the year? 7. What is the expected rate of change of HIV test consumption for other uses? 	N/A	<ol style="list-style-type: none"> 1. How many clients were tested for HIV in the past year³ for the other use(s) you are quantifying? 2. What is the percentage expected rate of change in testing for the other use(s) you are quantifying? 3. What is the HIV prevalence rate for clients tested for the other use(s) you are quantifying? 4. What is the average discordance rate between the screening and confirmatory tests? 5. What is the testing protocol for the other use(s) you are quantifying? 	<ol style="list-style-type: none"> 1. How many clients are targeted to be tested for HIV for the other use(s) you are quantifying? 2. What is the HIV prevalence rate for clients tested for the other use(s) you are quantifying? 3. What is the average discordance rate between the screening and confirmatory tests? 4. What is the testing protocol for the other use(s) you are quantifying?
Quality Control and Wastage Factors			
<ol style="list-style-type: none"> 1. What percentage of each brand of test will be used for quality control purposes? 2. What percentage of each brand of test will be wasted through expiry, faulty product, etc.? 			
Service Capacity			
<ol style="list-style-type: none"> 1. For the other use(s) you are quantifying, what is the total number of technicians conducting HIV tests? 2. How many days a year, on average, will a technician conduct HIV tests for the other use(s) you are quantifying? 3. On average, how many HIV tests for the other use(s) you are quantifying will a technician conduct per day? <p style="text-align: center;">- OR -</p> <ol style="list-style-type: none"> 4. If reliable service capacity data is not available, discuss with key informants the testing capacity for the other use(s) you are quantifying. Using this information, determine the maximum number of tests that can be conducted for the use(s) during the year you are quantifying. <p>If an ELISA/Blot is picked for the test kit selection—</p> <ol style="list-style-type: none"> 5. What is the yearly laboratory machine capacity for conducting the HIV test indicated in the product selection? 			

ADJUST DEMAND FOR QUALITY CONTROL AND WASTAGE**Quality control**

Some HIV tests require that additional tests be conducted to ensure the quality of the tests and the testing procedure. The number of tests required for quality control is a percentage of the total number of tests conducted. This factor varies among brands of tests. Some have an internal control feature and do not require additional tests.

Wastage

To fill the pipeline and to ensure a full supply of HIV tests, it is important to adjust the demand to compensate for tests that will not reach the service delivery point. The wastage factor is the estimated percentage of a brand of test that will expire, become damaged, lost, or found defective.

If a forecasting methodology other than logistics is used, adjust the resulting demand for quality control and wastage of tests. To adjust for quality control and wastage, use the following calculation:

$$\text{(Demand)} \times [1 + (\text{quality control factor} + \text{wastage factor})]$$

= demand adjusted for quality control and wastage.

Use a 10 percent wastage factor as the default value if actual wastage factors are not known or cannot be accurately estimated.

MEASURE HIV TESTING CAPACITY AND COMPARE TO FORECASTED DEMAND

After adjusting forecasted demand for quality control and wastage, you must measure the program's HIV testing capacity for each of the uses of HIV tests.

HIV counseling and testing capacity is affected by skill levels of staff, staff availability, availability of HIV test kits and related supplies, and availability of functioning equipment for tests requiring use of equipment.

Using the information from the answers to the service capacity questions in tables 2–8, and determine the HIV counseling and testing capacity for each use of HIV tests. The counseling capacity measure is relevant for VCT, PMTCT, and testing of HIV-exposed babies. It may also be relevant for blood safety and sentinel surveillance if these programs do linked testing.

To calculate capacity for each use:

$$\text{(Total number of technicians conducting HIV testing)} \times \text{(number of days per year on average that a technician will conduct HIV testing for the specified use)} \times \text{(average number of tests a technician will conduct per day for the specified use)}$$

= HIV testing capacity for that use.

If reliable service capacity data is not available, gather testing statistics for a recent past period and discuss these with key informants to arrive at a projected testing capacity for the program to be used for the quantification. If ELISA tests are used, the availability of functioning testing machines will also be part of the testing capacity measure, as will the availability of ELISA qualified technicians.

Compare the HIV testing capacity to the HIV tests forecasted demand figures. If the HIV testing capacity is equal to or larger than the forecasted demand figure, testing capacity does not pose a constraint.

If the forecasted demand figures are higher than the testing capacity, and the testing capacity cannot be significantly increased, the demand figures should be adjusted downward to a level commensurate with testing capacity.

The quantity resulting after the forecasted demand is adjusted for quality control, wastage, and service capacity is referred to as the adjusted demand.

D. Estimate Quantities Required

After calculating adjusted demand, it is necessary to estimate the quantities of HIV tests actually required to both meet the adjusted demand *and* to fill the pipeline to ensure a continuous supply to clients. It is also in this phase of quantification that one calculates the cold (2–8°C) storage space and room temperature (8–30°C) storage space required for the HIV tests. These space requirement figures are then compared to the actual storage space available at the level at which the tests will enter the program.

To estimate quantities required, obtain answers to the following questions:

1. What is the average monthly adjusted demand for each brand of test?
2. What is the average lead time in months for each brand of HIV test to be used in the program? (Lead time is defined as the time from when an order is placed until the tests arrive and are available for use. If the test kits are being imported, be sure to include time for customs clearance and inspection, and for testing if the kits are to be assessed for quality before being released for use.)
3. What is the desired level of buffer stock in months for each brand of test?
4. What is the volume of each brand of HIV test kit to be stored and distributed?
5. Which of the HIV test kits requires cold storage?
6. What is the volume of available cold storage and room temperature storage space at the level at which the HIV tests will enter the program?
7. What is the likely number of shipments of each brand of HIV test per year?
8. How much useable stock of each brand of HIV test is on hand at all levels of the system? (Subtract the number of tests on hand that will likely expire before use at current usage rates from the stock on hand figure.)
9. What quantity of each brand of HIV test is already on order from the suppliers? (Subtract the number of tests on order that will likely expire before use at current usage rates from the stock on order figure.)

The following are the calculations for estimating quantities required:

- (a) **(Adjusted demand quantity for each brand of HIV test for one year) × (12 months)**
= average monthly adjusted demand (AMAD) for each brand.
- (b) **(Lead time for each brand of HIV test in months) × (AMAD for each brand)**
= lead time stock for each brand of test.
- (c) **(Desired buffer stock for each brand of HIV test in months) × (AMAD for each brand of HIV test)**
= buffer stock for each brand of test.

Note: Because of the short shelf life of most HIV test kits, lead times must be kept very short, and buffer stocks must be kept at the minimum possible levels. No separate calculation is made for desired end of year stock as it is assumed to be covered by the lead time and buffer stock allowances.

- (a) **For each brand of test: (adjusted demand) + (lead time stock) + (buffer stock) - (usable stock on hand at all levels of the program) - (usable stock on order) = quantity required.**
- (b) **To calculate the volume at entry level for each brand of test: (adjusted demand + lead time stock + buffer stock for each brand) × (number of each brand of tests in a kit) × (volume of one HIV test kit of each brand required) = total volume of each brand of HIV test.**
- (c) **(Volume of brand1 test requiring cold storage + volume of brand2 test requiring cold storage + volume of brandN test requiring cold storage) × (estimated number of shipments for the year of tests requiring cold storage) = cold storage requirement for HIV tests at the entry level.**
- (d) **(Volume of brand1 test requiring room temperature storage + volume of brand2 test requiring room temperature storage + volume of brandN test requiring room temperature storage) × (estimated number of shipments for the year of tests requiring room temperature storage) = room temperature storage requirement for HIV tests at the entry level.**
- (e) Compare the volume per shipment of tests requiring cold storage and tests requiring under 30°C to the available space of both types.
- (f) If the available cold storage space and the available under 30°C storage space are the same as or larger than the expected shipment volumes plus buffer stock volume, storage at entry level does not pose a constraint.
- (g) If the available cold storage space or the available under 30°C, storage space is less than the volume of each shipment, advise the program managers that the storage space or the number of shipments must be increased so that each shipment can be properly stored upon arrival.

E. Calculate Financial Requirements

To calculate financial requirements for the quantities of tests required, the quantifier must obtain answers to the following questions:

1. What is the estimated cost per test kit of each brand of kit?
2. What is the estimated cost for freight and insurance for the required volume/value of HIV tests if freight and insurance costs are not already included in the cost per test kit?
3. What are the estimated customs duties and clearance costs for the required volume/value of HIV tests?
4. What are the direct storage and distribution costs on this volume/value of HIV tests?

To estimate the cost of the total numbers of HIV tests required:

- (a) Divide the required quantity of each brand of test by the number of tests per kit for that brand of test to determine the number of test kits required.
- (b) Discuss with key informants and review past purchase records to determine the likely cost per kit for each brand of kit, and/or

Consult standard price references, e.g., *Sources and prices of selected drugs and diagnostics for people living with HIV/AIDS*: June 2003. UNICEF, UNAIDS, WHO, and *Medecins Sans Frontieres*, to determine estimated costs per kit.

- (c) Multiply the cost per kit for each brand times the number of kits of each brand to determine the total cost for each brand of test kit.
- (d) Add these totals to determine the grand total financial requirement for all HIV tests for the year for the program. (Be cautious when you estimate the prices of test kits for the quantification. It is best to use a range of prices because often it is not known what prices will actually be obtained when the kits are procured.)
- (e) Determine the cost of insurance and freight for this volume/value of kits, if applicable.
- (f) Determine the costs of customs duties and customs clearance for this volume/value of HIV tests and add this amount to the financial requirements.
- (g) Determine any direct storage and distributions costs on this volume/value of HIV tests and add this amount to the financial requirements.

It is important to consider the insurance and freight costs, customs-related costs, and direct storage and distribution costs at the quantification stage. This will help ensure that program managers are aware of these costs, and can make provisions for them prior to the arrival of the HIV tests into the program. If these costs are not budgeted for in advance, there is a danger of the tests being delayed in customs clearance and in the distribution pipeline, resulting in loss of product through expiration.

If the main purpose of the quantification is to estimate financial requirements to request funding, the quantification ends at this point.

F. Reconcile Available Funding and Quantities Required

To reconcile available funding and quantities required, you must ask the following questions:

1. What are the sources of funding for HIV tests?
2. How much funding is available from each source of funding for this quantification period?
3. Is funding from some sources available only for specific uses of HIV tests?

With the answers to these statements:

- (a) Compare the financial requirements for HIV tests to the funding available for HIV tests from government sources and donors.
- (b) If available funding is greater than the financial requirements for the tests, procure only the quantities required. Do *not* order additional tests just to use all the available funds as this would probably result in financial losses through expiration of the tests.
- (c) If available funding is less than the financial requirements for the quantities of tests required, advise program managers to seek additional funding.
- (d) If additional funding cannot be secured, advise program managers that they must make decisions on the priorities for HIV testing for various uses to determine the quantities to procure.

In situations of non-full supply of HIV test kits, the budget reconciliation step typically involves prioritizing the purposes, e.g., blood safety, VCT, PMTCT, sentinel surveillance, clinical diagnosis, and other uses for the kits and reduction of quantities to be procured to fit available funds. It could also involve revisiting previous decisions regarding protocol. But, regardless of whether you change the protocol or keep the same one, be sure to procure kits in the proper proportion to ensure that the protocol can be completed.

G. Present Findings to Decision Makers

After the preliminary quantification is completed, it is recommended that the persons doing the quantification convene a validation workshop with representatives of all stakeholders in HIV testing. In this workshop the methodologies, assumptions, and outcomes of the quantification should be presented and reviewed. Participants should comment on the findings, correct any assumptions that are not valid, and, to the extent possible, reach a consensus on the quantities required and the financial requirements.

You must then present the validated quantification findings to top decision makers in an easily digestible form. In addition to a written report with an executive summary covering any major issues, it is desirable to make a presentation to top management where they have an opportunity to ask for clarifications. If available funding is less than the financial requirements for the quantity required, this meeting should serve as a forum for discussing the possibility of securing additional funding. If it is clear that additional funding will not be forthcoming, this meeting should serve as a forum for determining priorities for uses of HIV tests. Ideally, this meeting should result in decisions on quantities to procure for each brand/type of HIV test. To the greatest extent possible, HIV/AIDS program staff should present or participate in the presentation to top decision makers to show their involvement and buy-in to the findings.

Program managers should be advised of the quantities to be procured, and should ensure that adequate storage and distribution arrangements are in place at all lower levels of the system.

The selection, procurement, storage, distribution, and end use of HIV tests are not covered in this guide. However, there are several points related to these activities that are worth mentioning:

1. All other technical factors being equal, preference in selection should be given to HIV tests that do not require cold storage, have the longest shelf lives, and are as self-contained with peripheral supplies as possible.
2. The emphasis in procurement should be on developing supplier relationships that allow for frequent shipments of relatively small quantities of freshly manufactured kits. When possible, the purchasing contract should allow for accelerating or slowing down the delivery of test kits to the program depending on the actual consumption of the test kits.
3. The shipment schedule for the HIV tests must reflect the lead time and shelf life for each product as well as current storage and distribution capacity of the logistics system. For example, tests with a short shelf life and cold chain storage requirements may have to be manufactured and shipped to a country at more frequent intervals than kits with a longer shelf life that can be stored at room temperature. The in-country pipeline for these items would need to be shorter than for drugs and other supplies, and the test kits would need to be delivered to service delivery points more frequently.
4. Because of their short shelf life, HIV test kits ideally should be distributed from the central level straight to the service delivery points with no intervening layers of storage, handling, or paper work.

4. Automating Quantification

Because of the multiple uses of HIV tests, the varying methodologies that can be used to forecast demand, the potentially large number of brands of tests that might be available, and the benefit of generating multiple quantification scenarios for comparison, e.g., low, medium, and high growth in testing rates, the actual calculations can become relatively complex. There are advantages to having portions of the process automated.

John Snow, Inc., has developed ProQ, a software program for the quantification of HIV test requirements.

For information about ProQ contact:

ProQ Program Associate
JSI/DELIVER
1616 N. Fort Myer Dr.
11th Floor
Arlington, VA 22209-3100
USA
Tel +1 703-528-7474
Fax. +1 703-528-7480
deliver.jsi.com

5. End Notes

- ¹ At the AIDS Information Center in Uganda, when clients were asked to return at a later date, 25 percent of clients failed to receive their test results. With the switch to rapid tests and same-day results, more than 99 percent of clients now receive their results and post-test counseling on the same day. *Knowledge is power: Voluntary HIV counseling and testing in Uganda*; UNAIDS Case Study, June 1999; UNAIDS Best Practice Collection.
- ² This statement on accounting for periods of stockouts of HIV tests is most applicable for a use such as blood safety, wherein the tests would have been used if available, but once they were not used there would not be a “pent up” demand for the tests. For uses such as VCT, PMTCT, testing of HIV-exposed babies, and testing for clinical diagnosis, a certain amount of the demand for tests during a period of stockouts would have been delayed, but then met once supplies were again available. In these latter cases, adding a number of estimated tests for the period of stockouts might result in an overstatement of consumption.
- ³ The “year” is the most recent 12 months for which data is available.
- ⁴ Use the same “year” when answering logistics questions 3–6.
- ⁵ If blood donors recruited through campaigns have significantly lower HIV prevalence than donors recruited by families of patients, one can quantify separately for each group. The HIV-positive rate for the general population can be applied to the donors recruited by families of patients.

References

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World Health Organization (WHO). 2001. *Guidelines for Using HIV Testing Technologies in Surveillance: Selection, Evaluation, and Implementation*. WHO/CDS/CSR/EDC/2001.16 or UNAIDS/01.22E.

World Health Organization (WHO). 2002. *HIV/AIDS Drugs and Diagnostics of Acceptable Quality*. <http://www.who.int/medicines/organization/par/edl/access-hivdrugs.shtml>

6. Appendix: Methodologies

Logistics: In this methodology the forecast is based on stock consumption rates. This methodology is most useful in mature, stable testing programs that have a full supply of test kits and where reliable data is available. It is useful only in a system where prior consumption can be determined or at least extrapolated. One caution on using this methodology is that data on past consumption of HIV tests may not be predictive of future use because past testing was often undertaken on a pilot or small-scale basis, often by nongovernmental organizations (NGO). Also, if the program has experienced frequent stockouts of test kits, the consumption figures might be understated relative to what consumption would have been if the test kits had been available in full supply.

Question 1—Determine how many of each brand of test were used in the past 12 months for each of the seven uses of the tests. If there were frequent periods of stockouts of HIV tests, make an estimate of the number of tests that would have been consumed for these periods of stockouts. Add this number to the estimated number of tests used in the past year.² This is possible if the program has a very well-designed and well-executed information system with reports that provide this information. This is likely to be the case in only the most mature and well-supported programs.

If this information is not available or is of questionable reliability, go to question 2.

Question 2—Examine records and reports and discuss with key informants to determine which level of the health care system, e.g., SDP, district, provincial, or regional, has the most complete logistics records and reports for HIV tests.

Questions 3–6—For that level of the system, answer questions 3–6.

3. For this level of the logistic system, what was the beginning inventory for each brand of test at the start of the year?
4. For this level of the logistic system, what were the receipts for each brand of test for the year?
5. For this level of the logistic system, what were the losses and adjustments for each brand of test for the year? (Note: This includes any changes to the inventory records to reflect losses or transfers or to correct record keeping errors. It can be a positive or negative number.)
6. For this level of the logistic system, what was the ending inventory for each brand of test for the year?

Calculate estimated consumption for each brand:

$$\begin{aligned} & \text{(Beginning inventory + receipts) } \pm \text{ (losses/adjustments)} \\ & - \text{ ending inventory} \\ & = \text{ estimated consumption for the year.} \end{aligned}$$

Compare the consumption of tests in question one to the consumption resulting from the calculations in questions 3-6, and select the figure you wish to use for this quantification. Generally, you should select the consumption figure based on what you perceive to be the most reliable data.

Question 7—Discuss with key informants the expected rate of change (increase or decrease) in use of HIV tests for the year you are quantifying. Take into account economic, political, and programmatic factors such as information campaigns, expansion of service networks, funding shortfalls, etc., that could raise or lower demand for HIV testing for the forecast period.

$$\begin{aligned} & \text{The estimated consumption of each brand of test for the past year} \\ & \times \text{ (1 + the change factor in decimal form)} \\ & = \text{ estimated demand for the year you are quantifying.} \end{aligned}$$

If the program experienced frequent stockouts of HIV test kits, how many days on average were facilities stocked out of HIV tests?

**(Estimated consumption for the year) ÷ (number of days the facilities had tests in stock)
× (number of days the facilities were stocked out of tests)
= estimated number of tests that would have been consumed during periods of the stockout.**

Add this number to the (estimated consumption for the year).²

Demographic/Morbidity: In this methodology, the forecast is based on the population of the program service areas and the HIV prevalence rates in these areas. The demographic/morbidity methodology is often used for new programs where little or no historical logistics or service statistics data is available.

BLOOD SAFETY

Question 1—Through census or other records, estimate the population of the areas served by the blood transfusion centers and by hospitals that collect blood.

Question 2—Discuss with the blood transfusion services what percentage of the service area population will likely donate blood. Discuss with program managers and come to an agreement on this figure.

Question 3—Discuss with key informants and review records to obtain information on how many times a year a donor donates blood.

Question 4—Review records and reports of blood safety testing results to determine the HIV prevalence rate among blood donors. If the blood donor screening program is effective, this HIV prevalence rate should be significantly lower than the HIV prevalence rate in the general population.

Question 5—Discuss with key laboratory personnel and program managers the discordance rate between the screening and confirmatory HIV tests.

Question 6—From published guidelines for blood safety, discussions with key informants, and field observations, determine which of the HIV testing protocols are used for blood safety.

If testing protocol S3 is in use, which is three tests conducted serially, demand for HIV tests would be calculated as follows:

(Population of the service area) × (% of population donating blood) × (times per year that a donor donates blood)
= estimated units of blood to be collected
= demand for HIV screening tests.

(Units of blood to be collected) × (blood donor HIV prevalence rate)
= demand for HIV confirmatory tests.

(Demand for HIV confirmatory tests) × (discordance rate between HIV screening and confirmatory tests)
= demand for HIV tie breaking tests.

If parallel testing protocol P1, two tests in parallel and one tie-breaking test for discordant results, is being used for blood safety, the demand for both tests A and B would equal the estimated units of blood to be collected. The demand for test C would equal the number of blood units collected times the discordance rate between tests A and B. Variations on this formula would apply to the other parallel testing protocols.

VOLUNTARY COUNSELING AND TESTING (VCT)

The demand for HIV tests for VCT under a S3 testing protocol would be as follows:

(Population of service area) × (% of population likely to come for VCT counseling)
 × (% of counseled clients likely to accept testing)
 = demand for HIV screening tests.

(Demand for HIV screening tests) × (HIV prevalence rate among VCT clients)
 = demand for HIV confirmatory tests.

(Demand for HIV confirmatory tests) × (discordance rate between screening and confirmatory tests)
 = demand for HIV tie breaking tests.

As with blood safety, there would be variations on these quantities if parallel testing protocols were being used.

PREVENTION OF MOTHER-TO-CHILD TRANSMISSION (PMTCT)

The demand for HIV tests for PMTCT under the S3 testing protocol would be as follows:

(Women of reproductive age in PMTCT site service areas) × (pregnancy rate in the service areas) × (% of pregnant women making one ANC visit to program facilities)
 × (% of ANC clients likely to request HIV counseling) × (% of counseled women likely to accept HIV testing)
 = demand for HIV screening tests for PMTCT.

(Demand for HIV screening tests for PMTCT) × (HIV prevalence rate among PMTCT clients)
 = demand for HIV confirmatory tests.

(Demand for HIV confirmatory tests) × (discordance rate between screening and confirmatory tests)
 = demand for HIV tie breaking tests.

TESTING OF HIV-EXPOSED BABIES

The demand for HIV tests for testing HIV-exposed babies under the S3 testing protocol would be as follows:

(Number of babies born to HIV+ PMTCT clients) × (% of babies of HIV+ PMTCT clients who will be brought for HIV testing at age 9 months)
 = A, the demand for HIV screening tests for HIV-exposed babies tested at age 9 months.

A × (HIV prevalence rate of HIV-exposed babies)
 = B, demand for confirmatory tests for HIV-exposed babies tested at age 9 months.

B × (discordance rate between screening and confirmatory tests)
 = C, demand for tiebreaker tests for HIV-exposed babies tested at age 9 months.

B × (% of babies testing positive at age 9 months who will be brought for retesting at age 18 months)
 = D, demand for HIV screening tests for HIV-exposed babies tested at age 18 months.

D × (HIV prevalence rate of HIV-exposed babies testing at age 18 months)
 = E, demand for HIV confirmatory tests for HIV-exposed babies testing at age 18 months.

E × (discordance rate between the screening and confirmatory tests)
 = F, demand for tiebreaker tests for HIV-exposed babies tested at age 18 months.

A + D = total demand for screening tests for HIV-exposed babies for the year for which you are quantifying.

B + E = total demand for confirmatory tests for HIV-exposed babies for the year you are quantifying.

C + F = total demand for tiebreaker tests for HIV-exposed babies for the year you are quantifying.

A very small additional quantity of tests would be required for retesting babies who were HIV-negative at the time of the 9 or 18 month test but who were still breastfeeding at that time or who had discontinued breastfeeding just shortly before being tested at age 9 or 18 months. These babies would be retested three months after being weaned from breast milk.

Because of the testing intervals of 9 months, not all the tests quantified using the above formula would be consumed in a one-year period. However, for quantification purposes, it is assumed that the quantities calculated would be consumed in one year. This assumption is made because testing of HIV-exposed babies from the previous year, because of the 9-month testing intervals, would “spill over” into the year for which you are quantifying, thereby offsetting the number of tests quantified for this year that will spill over into the following year.

CLINICAL DIAGNOSIS

The demand for HIV tests for clinical diagnosis under the S3 testing protocol would be as follows:

(Population of clinic service areas) × (% if population is likely to access program clinics) × (% of population accessing program clinics who will show signs and symptoms of AIDS)

= demand for HIV screening tests for clinical diagnosis.

(Demand for HIV screening tests for clinical diagnosis) × (HIV prevalence rate among clinic patients)

= demand for HIV confirmatory tests for clinical diagnosis.

(Demand for HIV confirmatory tests for clinical diagnosis) × (discordance rate between screening and confirmatory tests)

= demand for HIV tie breaking tests for clinical diagnosis.

Service Statistics: This methodology is based on the projection of past levels of testing.

BLOOD SAFETY

Question 1—Determine from records and reports the approximate number of units of blood collected in the past year.

Question 2—If information is not available on units collected, determine from records and reports the approximate number of units of blood transfused in the past year.

Question 3—Interview key informants in the blood transfusion services to determine the approximate discard rate of blood units collected.

To use the information gathered for questions 2 and 3 to estimate the number of blood units collected in the past year, divide the number of blood units transfused by $(1 - \text{the discard rate}) = \text{number of units collected}$.

The demand for HIV tests for blood safety using testing protocol S3 is calculated as follows:

$(\text{Units of blood collected in the past year}) \times (1 + \text{expected rate of change in blood collection})$
 $= \text{units of blood to be collected in the forecast year}$
 $= \text{demand for HIV screening tests.}$

$(\text{Demand for screening HIV tests}) \times (\text{HIV prevalence rate among blood donors})$
 $= \text{demand for HIV confirmatory tests for blood safety.}$

$(\text{Demand for confirmatory tests for blood safety}) \times (\text{discordance rate between screening and confirmatory tests})$
 $= \text{demand for HIV tie breaking tests for blood safety.}$

VOLUNTARY COUNSELING AND TESTING

Under protocol S3, the tests required for VCT would be calculated as follows:

$(\text{VCT clients tested in the past year}) \times (1 + \text{expected rate of change in VCT testing})$
 $= \text{demand for HIV screening tests for VCT in the year you are quantifying.}$

$(\text{Demand for screening tests for VCT}) \times (\text{HIV prevalence rate among VCT clients})$
 $= \text{demand for HIV confirmatory tests for VCT.}$

$(\text{Demand for HIV confirmatory tests for VCT}) \times (\text{Discordance rate between screening and confirmatory tests})$
 $= \text{demand for HIV tie breaking test for VCT.}$

PREVENTION OF MOTHER-TO-CHILD TRANSMISSION

The demand for HIV tests for PMTCT under testing protocol S3 is calculated as follows:

$(\text{Number of pregnant women who were tested for HIV in the past year in the PMTCT program})$
 $\times (1 + \text{expected rate of change in PMTCT testing})$
 $= \text{demand for HIV screening tests for PMTCT in the year for which you are quantifying.}$

$(\text{Demand for screening tests for PMTCT}) \times (\text{HIV prevalence rate among PMTCT clients})$
 $= \text{demand for HIV confirmatory tests for PMTCT.}$

$(\text{Demand for HIV confirmatory tests for PMTCT}) \times (\text{Discordance rate between HIV screening and HIV confirmatory tests})$
 $= \text{demand for HIV tiebreaker tests for PMTCT.}$

TESTING OF HIV-EXPOSED BABIES

Other Uses

Under testing protocol S3 the tests required for testing of HIV-exposed babies and for other uses would be calculated in the same manner as for VCT and PMTCT.

Target: This methodology is based not on the need for the tests in a population, but on the number of tests program managers believe are necessary, e.g., for sentinel surveillance, special studies, or training, or on the number of tests that program managers believe the program can conduct given the number of available staff and other resources. Under this methodology—

**The number of clients or blood samples targeted
= the demand for HIV screening tests.**

**(Demand for HIV screening tests) × (HIV prevalence rate for the target group)
= demand for HIV confirmatory tests.**

**(Demand for HIV confirmatory tests) × (discordance rate between screening and confirmatory tests)
= demand for HIV tie breaking tests.**

For sentinel surveillance, the WHO protocol recommends only one test, so no confirmatory test is used. Some number or percentage of screening samples are randomly selected for quality control testing. If these quality control test results differ from the screening test results, further tests may be used for validation.